

support for amendment to claim 4 is found in original claims 1 and 4 and at paragraph 0009. Support for amendment to claim 5 is presented in original claim 5 and paragraphs 0026 and 0027. Support for amendment to claim 6 is found in original claim 6 and paragraph 0040. Support for amendment to claim 9 is presented in original claim 9 and at paragraph 0022. No issue of new matter is introduced by these amendments.

Support for new claims 32-34 is provided throughout the originally filed specification. Specifically, support for claims 32-34 is provided in claims 16, 21, and 25, respectively, and at paragraph 0015. No new matter has been introduced into the application by way of new claims 32-34, and the Examiner is respectfully requested to enter these claims.

A marked up version of the claims is attached hereto.

The Examiner has rejected claims 4-6, 12, and 13 under 35 U.S.C. §112, second paragraph, for allegedly being indefinite. Applicant's understanding of the Examiner's position is that claims 4-6 are indefinite as written. The revision to claim 4 to clarify the association of the all trans retinoic acid with lipid particle carriers as contemplated by applicant is believed to favorably respond to this objection and to be curative of it. The revision to claim 5, wherein the mode of administration is clarified, and the revision to claim 6, wherein the frequency of administration is more clearly set forth, are believed to favorably address these objections. Claim 6 has also been amended to recite the phrase "wherein the composition comprising at least one interferon and a retinoid ..." for which antecedent basis is found in claim 1. With regard to the Examiner's rejection of claims 12 and 13 for recitation of "cancerous", applicant respectfully directs the Examiner to independent claims 1 and 8, wherein antecedent basis for the term "cancerous cells" is presented. In view of the above, applicant submits that the rejection of claims 12 and 13 under 35 U.S.C. §112, second paragraph, is improper and should be withdrawn. Accordingly, applicant believes that the Examiner's objections based on indefiniteness have been resolved by the above amendments and comments, and withdrawal of this ground of rejection particularly as it may apply to the claims if amended as proposed, is believed to be in order and is requested.

The Examiner has rejected claim 9 under 35 U.S.C. §103(a) as allegedly unpatentable over Kelly et al. (2000 Mar, Clinical Cancer Research 6:838-846). Applicant asserts that claim 9 as presently amended is not rendered obvious by the disclosure of Kelly et al. There is no

teaching or suggestion in Kelly et al. relating to a kit directed to the combined use of all-trans retinoic acid and interferon or to a therapeutic utility of such a combination. Thus, this reference fails to render obvious the kit of instant claim 9. Applicant, therefore, respectfully requests that the rejection of claim 9 under 35 U.S.C. §103(a) over Kelly et al. be withdrawn.

Concurrently with the submission of the instant Amendment and Response, Applicant has assembled copies of additional references that Applicant wishes to make of record in the present application, and is filing the same in a Supplemental Information Disclosure Statement that is being mailed separately herefrom, together with the applicable fee of \$180.00. A copy of the transmittal and the associated Forms PTO-1449 are attached hereto for reference.

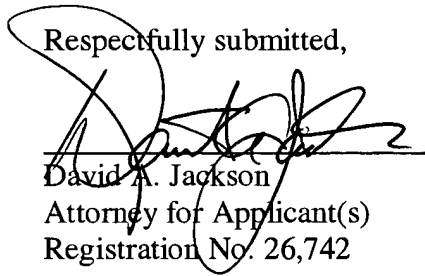
#### **Fees**

No additional fees are believed to be necessitated by the instant response. However, should this be in error, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment, or to credit any overpayments.

#### **Conclusion**

Applicant submits that the claims as amended and new claims are in condition for allowance, and accordingly, reconsideration and withdrawal of the outstanding grounds of rejection, and early allowance of the claims as amended is believed to be in order and is courteously solicited.

Respectfully submitted,



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June 13, 2003

Attachments: Marked-up copy of amended claims  
Courtesy copy of Supplemental IDS

**MARKED-UP COPY OF THE AMENDED CLAIMS**

**IN THE CLAIMS:**

The claims have been amended as follows:

4. (Amended Twice) The method of Claim 1 [3] wherein the lipid carrier particles comprise all-trans retinoic acid, lipid, and a triglyceride: wherein a molar ratio of retinoid to lipid is at least about 15:85; the triglyceride is at least about 15% by weight of the composition; and the composition is stable in an aqueous environment.
5. (Amended Twice) The method of Claim 1 comprising administering said retinoid composition by intravenous infusion [in at least one dose over a period of at least one-half hour].
6. (Amended Twice) The method of Claim 1 wherein [said retinoid] the composition comprising at least one interferon and a retinoid is administered at a frequency from daily to about 3 out of 7 days per week [no greater than about every other day].
9. (Amended Once) A therapeutic treatment kit for the treatment of cancer comprising interferon, all-trans retinoic acid [retinoid] and instructional materials for the combined use of said all-trans retinoic acid [retinoid] and interferon[.,].